

AMENDED IN ASSEMBLY MARCH 24, 2010

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

**ASSEMBLY BILL**

**No. 2112**

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**Introduced by Assembly Member Monning**

February 18, 2010

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An act to add Part 2.7 (commencing with Section 60) to Division 1 of the Civil Code, *and to amend Section 130202 of the Health and Safety Code*, relating to privacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 2112, as amended, Monning. Prescription Record Privacy Act.

The Confidentiality of Medical Information Act prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, using for marketing, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, unless a specified exception applies.

This bill would enact the Prescription Record Privacy Act, prohibiting a person from knowingly disclosing or using regulated records that include prescription information containing individual identifying information for marketing a prescribed product, as provided, *except when information may be transferred to another entity, as provided, and in accordance with other state and federal laws*. The act would not prohibit conduct involving the collection, use, transfer, or sale of regulated records for marketing purposes if the data is aggregated, does not contain ~~individually individual~~ identifying information, and the data cannot reasonably be used to obtain ~~individually individual~~ identifying information. This bill would also require that any person ~~who~~ *that* knowingly fails to comply with these provisions be subject to an

administrative penalty of at least \$10,000 *and not more than \$50,000 per violation.*

This bill would authorize the Secretary of California Health and Human Services to adopt regulations to implement these provisions. This bill would ~~also~~ require the office of the Attorney General to enforce payment of penalties for violations of these provisions, as provided. *This bill would also authorize the Office of Health Information Integrity, upon receipt of a complaint of a violation of these provisions, to conduct an administrative hearing, in accordance with the administrative adjudication provisions set forth in the Administrative Procedure Act, and to assess an administrative fine against a person or entity found to have committed a violation of these provisions.*

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

1 SECTION 1. Part 2.7 (commencing with Section 60) is added  
2 to Division 1 of the Civil Code, to read:

3

4 PART 2.7. PRESCRIPTION RECORD PRIVACY ACT

5

6 60. This part may be cited as the Prescription Record Privacy  
7 Act.

8 60.5. It is the intent of the ~~legislature~~ *Legislature* to safeguard  
9 the confidentiality of prescribing information, protect the integrity  
10 of the doctor-patient relationship, maintain the integrity and public  
11 trust of the medical profession, combat vexatious and harassing  
12 sales practices, restrain undue influence exerted by pharmaceutical  
13 industry marketing representatives over prescribing decisions, and  
14 further the state's interest in improving the quality and lowering  
15 the cost of health care. The ~~legislature~~ *Legislature* intends to  
16 regulate the monitoring of prescribing practices only for  
17 commercial marketing purposes by companies selling prescribed  
18 products. The intent is not to regulate monitoring for other uses,  
19 such as quality control, research unrelated to marketing, or use by  
20 governments or other entities not in the business of selling health  
21 care products.

22 61. For purposes of this part:

1 (a) “Bona fide clinical trial” means any research project that  
2 prospectively assigns human subjects to intervention and  
3 comparison groups to study the cause and effect relationship  
4 between a medical intervention and a health outcome, has received  
5 approval from an appropriate institutional review board, and has  
6 been registered at <http://ClinicalTrials.gov> prior to commencement.

7 (b) “Individual identifying information” means information that  
8 directly or indirectly identifies a prescriber or a patient in this state,  
9 indicates where the information is derived from, or relates to a  
10 prescription for any prescribed product.

11 (c) “Marketing” means any activity by a company making or  
12 selling prescribed products, or by that company’s agent, intended  
13 to influence prescribing or purchasing choices of its products,  
14 including, but not limited to:

15 (1) Advertising, publicizing, promoting, or sharing information  
16 about a product.

17 (2) Identifying individuals to receive a message promoting use  
18 of a particular product, including, but not limited to, an  
19 advertisement, brochure, or contact by a sales representative.

20 (3) Planning the substance of a sales representative visit or  
21 communication or the substance of an advertisement or other  
22 promotional message or document.

23 (4) Evaluating or compensating sales representatives.

24 (5) Identifying individuals to receive any form of gift, product  
25 sample, consultancy, or any other item, service, compensation, or  
26 employment of value.

27 (6) Advertising or promoting prescribed products directly to  
28 patients.

29 (d) “Person” means a business, individual, corporation, union,  
30 association, firm, partnership, committee, or other organization or  
31 group of persons.

32 (e) “Pharmacy” means any individual or entity licensed under  
33 state law to dispense prescribed products.

34 (f) “Prescribed product” includes a biological product as defined  
35 in Section 262 of Title 42 of the United States Code and a device  
36 or a drug as defined in Section 321 of Title 21 of the United States  
37 Code.

38 (g) “Regulated record” means information or documentation  
39 from a prescription written by a prescriber doing business in this  
40 state or a prescription dispensed in this state.

1 62. (a) No person shall knowingly disclose or use regulated  
2 records that include prescription information containing individual  
3 identifying information for marketing a prescribed product.

4 (b) A regulated record containing individual identifying  
5 information may be transferred to another entity, including to  
6 another branch or subsidiary of the same firm, only if it carries  
7 satisfactory assurance that the recipient will safeguard the records  
8 from being disclosed or used for a marketing purpose prohibited  
9 under this section *and only if the transfer is in accordance with*  
10 *other state and federal laws.*

11 (c) Regulated records containing individual identifying  
12 information may be disclosed, sold, transferred, exchanged, or  
13 used for nonmarketing purposes *only in accordance with other*  
14 *state and federal laws.*

15 (d) This section does not prohibit conduct involving the  
16 collection, use, transfer, or sale of regulated records for marketing  
17 purposes if:

18 (1) The data is aggregated.

19 (2) The data does not contain ~~individually~~ *individual* identifying  
20 information.

21 (3) There is no reasonable basis to believe that the data can be  
22 used to obtain ~~individually~~ *individual* identifying information.

23 (e) This section shall not prevent any person from disclosing  
24 regulated records to the identified individual as long as the  
25 information does not include protected information pertaining to  
26 any other person.

27 63. The Secretary of California Health and Human Services  
28 may adopt regulations as necessary to implement this part.

29 64. Any person ~~who~~ *that* knowingly fails to comply with the  
30 requirements of this part or regulations adopted pursuant to this  
31 part by using or disclosing regulated records in a manner not  
32 authorized by this part or its regulations, shall be subject to an  
33 administrative penalty of at least ten thousand dollars (\$10,000)  
34 per violation and not more than fifty thousand dollars (\$50,000)  
35 per violation, as assessed by the California Health and Human  
36 Services Agency. Each disclosure of a regulated record shall  
37 constitute a violation. The office of the Attorney General shall  
38 take necessary action to enforce payment of penalties assessed  
39 under this section. Minimum statutory penalties shall be set at ten

1 thousand dollars (\$10,000) per violation, notwithstanding Section  
2 125.9 of the Business and Professions Code.

3 64.5. In addition to any other remedy provided by law, a  
4 violation of this chapter shall be an unfair or deceptive act in trade  
5 or commerce and an unfair method of competition and may be  
6 enforced as an unfair business practice pursuant to Chapter 5 of  
7 Part 2 of Division 7 of the Business and Professions Code.

8 65. (a) The intent of this section is to ensure the confidentiality  
9 of data held by a state agency or its agent, which could be used to  
10 directly or indirectly identify a patient or a health care professional  
11 licensed to prescribe drugs, biological products, or medical devices.

12 (b) For the purposes of this section:

13 (1) "Individual identifying information" shall have the same  
14 meaning as in Section 61.

15 (2) "Prescribed product" includes a biological product as defined  
16 in Section 262 of Title 42 of the United States Code and a device  
17 or a drug as defined in Section 321 of Title 21 of the United States  
18 Code.

19 (3) "State health care program" means a program for which the  
20 state purchases prescribed products, including, but not limited to,  
21 a state pharmaceutical assistance program, or a program for state  
22 employees and their ~~dependants~~ *dependents*, individuals under the  
23 supervision of corrections, or state retirees and their ~~dependants~~  
24 *dependents* with the exception of the state medical assistance  
25 program (Medi-Cal).

26 (c) Records held by an agency administering a state health care  
27 program that include prescription information containing individual  
28 identifying information shall only be disclosed for the purposes  
29 allowed in Section 62.

30 (d) Any person who knowingly fails to comply with the  
31 requirements of this chapter or rules adopted pursuant to this part  
32 by using or disclosing regulated records in a manner not authorized  
33 by this part or its rules shall be subject to an administrative penalty  
34 of *at least ten thousand dollars (\$10,000) per violation* and not  
35 more than fifty thousand dollars (\$50,000) per violation, as  
36 assessed by the California Health and Human Services Agency.  
37 Each disclosure of a regulated record shall constitute a violation.  
38 The office of the Attorney General shall take necessary action to  
39 enforce payment of penalties assessed under this section.

1     65.5. (a) The intent of this ~~section~~ *part* is to ensure compliance  
2 with federal Medicaid law and regulations prohibiting the  
3 disclosure and use of Medicaid data, except to administer the  
4 Medicaid program, and to ensure that data held by the state agency  
5 or its agents that could directly or indirectly identify patients or  
6 health care professionals licensed to prescribe products be kept  
7 confidential.

8     (b) The State Department of Health Care Services, which  
9 administers the state medical assistance program (Medi-Cal) under  
10 subchapter C of Chapter 4 of Title 42 of the Code of Federal  
11 Regulations (Medicaid) or a Medicaid waiver approved by the  
12 Centers for Medicare and Medicaid Services, shall disclose records  
13 that include prescription information only as provided for under  
14 Section 431 of Title 42 of the Code of Federal Regulations and  
15 the *federal* Privacy Act of 1974. The department shall ensure that  
16 any agent or contractors with the department are informed of the  
17 limitations on redisclosure or use of the data provided for under  
18 applicable federal regulations and shall have policies and  
19 procedures for ~~insuring~~ *ensuring* compliance with this statute and  
20 federal regulations.

21     (c) Any person ~~who~~ *that* knowingly fails to comply with the  
22 requirements of this part or rules adopted pursuant to this part by  
23 using or disclosing regulated records in a manner not authorized  
24 by this part or its rules shall be subject to an administrative penalty  
25 of *at least ten thousand dollars (\$10,000) per violation and not*  
26 *more than fifty thousand dollars (\$50,000) per violation*, as  
27 assessed by the California Health and Human Services Agency.  
28 Each disclosure of a regulated record shall constitute a violation.  
29 The office of the Attorney General shall take necessary action to  
30 enforce payment of penalties assessed under this section.

31     66. If any provision of this act or its application to any person  
32 or circumstance is held invalid, the remainder of the act or the  
33 application of the provision to other persons or circumstances is  
34 not affected.

35     67. Nothing in this act shall be interpreted to regulate conduct  
36 that takes place entirely outside of the state.

37     67.5. Nothing in this act shall be interpreted to regulate the  
38 content, time, place, or manner of any discussion between a  
39 prescriber and ~~their~~ *his or her* patient, or a prescriber and any  
40 person representing a prescription drug manufacturer.

1     *SEC. 2. Section 130202 of the Health and Safety Code is*  
2     *amended to read:*

3     130202. (a) (1) Upon receipt of a referral from the State  
4     Department of Public Health, the office may assess an  
5     administrative fine against any person or any provider of health  
6     care, whether licensed or unlicensed, for any violation of this  
7     division in an amount as provided in Section 56.36 of the Civil  
8     Code. Proceedings against any person or entity for a violation of  
9     this section shall be held in accordance with *the* administrative  
10    adjudication provisions of Chapter 4.5 (commencing with Section  
11    11400) and Chapter 5 (commencing with Section 11500) of Part  
12    1 of Division 3 of Title 2 of the Government Code.

13    (2) Paragraph (1) shall not apply to a clinic, health facility,  
14    agency, or hospice licensed pursuant to Section 1204, 1250, 1725,  
15    or 1745 if Senate Bill 541 of the 2007–08 Regular Session is  
16    enacted and becomes effective on or before January 1, 2009.

17    (3) Nothing in paragraph (1) shall be construed as authorizing  
18    the office to assess the administrative penalties described in Section  
19    1280.15 of the Health and Safety Code.

20    ***(b) Upon receipt of a complaint under Part 2.7 (commencing***  
21    ***with Section 60) of Division 1 of the Civil Code, the office may***  
22    ***assess an administrative fine against any person or any provider***  
23    ***of health care, whether licensed or unlicensed, for any violation***  
24    ***of that part. Proceedings against any person or entity for a***  
25    ***violation of Part 2.7 (commencing with Section 60) of Division 1***  
26    ***of the Civil Code shall be held in accordance with the***  
27    ***administrative adjudication provisions of Chapter 4.5 (commencing***  
28    ***with Section 11400) and Chapter 5 (commencing with Section***  
29    ***11500) of Part 1 of Division 3 of Title 2 of the Government Code.***

30    ~~(b)~~

31    ***(c) The office shall adopt, amend, or repeal, in accordance with***  
32    ***the provisions of Chapter 3.5 (commencing with Section 11340)***  
33    ***of Part 1 of Division 3 of Title 2 of the Government Code, such***  
34    ***rules and regulations as may be reasonable and proper to carry out***  
35    ***the purposes and intent of this division, and to enable the authority***  
36    ***to exercise the powers and perform the duties conferred upon it***  
37    ***by this division not inconsistent with any other provision of law.***

38    ~~(e)~~

- 1     *(d)* Paragraph (3) of subdivision (a) shall only become operative
- 2     if Senate Bill 541 of the 2007–08 Regular Session is enacted and
- 3     becomes effective on or before January 1, 2009.